

# Exhibit

# B

**CT CORPORATION**  
A WoltersKluwer Company

**Service of Process  
Transmittal**

03/27/2006  
Log Number 511030242

**TO:** Stephen D. O'Sullivan  
Pfizer Inc.  
Arbor Lake Centre, 1751 Lake Cook Road  
Deerfield, IL, 60015

**RE: Process Served in California**

**FOR:** G. D. Searle & Co. (Former Name) (Domestic State: DE)  
G. D. Searle LLC (True Name)

**REC'D MAR 8 9 2006**

**ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:**

<b>TITLE OF ACTION:</b>	Beverly Haslam, etc., Pltf. vs. Pfizer Inc., et al., including G.D. Searle & Co., Dfts.
<b>DOCUMENT(S) SERVED:</b>	Letter Dated 03/24/06, Summons, Complaint, Return of Service
<b>COURT/AGENCY:</b>	California, U.S. District Court, Northern, . Case # C062145CRB
<b>NATURE OF ACTION:</b>	Wrongful Death - Regarding Bextra
<b>ON WHOM PROCESS WAS SERVED:</b>	C T Corporation System, Los Angeles, CA
<b>DATE AND HOUR OF SERVICE:</b>	By Courier on 03/27/2006
<b>APPEARANCE OR ANSWER DUE:</b>	Within 20 days
<b>ATTORNEY(S) / SENDER(S):</b>	Michael J. Miller Miller & Associates 105 North Alfred Street Alexandria, VA, 22314
<b>ACTION ITEMS:</b>	SOP Papers with Transmittal, via Fed Ex 2 Day, 790370416183
<b>SIGNED:</b>	C T Corporation System
<b>PER:</b>	Dianne Christman
<b>ADDRESS:</b>	818 West Seventh Street Los Angeles, CA, 90017
<b>TELEPHONE:</b>	213-627-8252

Page 1 of 1 / GG

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*Of Counsel*  
Nancy Guy Armstrong – MS

March 24, 2006

CT Services Corporation  
818 West 7<sup>th</sup> Street  
Los Angeles, CA 90017

**Re: Case # 3:06-cv-2145-CRB**

Dear Sir or Madam:

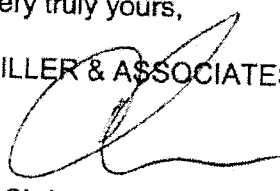
Enclosed for service please find a copy of the Summons, Civil Complaint, and Return of Service form in the above matter.

Kindly return the executed Return of Service form to me in the enclosed self-addressed stamped envelope.

Thank you for your time and attention to this matter.

Very truly yours,

MILLER & ASSOCIATES

  
J. Christopher Ide

JCI/ehd  
Enclosures

United States District Court  
NORTHERN DISTRICT OF CALIFORNIA

BEVERLY HASLAM, individually and on behalf  
of GLEN HASLAM, deceased

**SUMMONS IN A CIVIL CASE**

CASE NUMBER:

v.

PFIZER INC., PHARMACIA CORPORATION,  
and G.D. SEARLE, LLC

**C 06 2145**

**CRB**

TO: (Name and address of defendant)

G.D. Searle & Co., c/o  
CT Service Corporation  
818 West Seventh Street  
Los Angeles, CA 90017

**YOU ARE HEREBY SUMMONED** and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

Michael J. Miller  
Miller & Associates  
105 North Alfred Street  
Alexandria, VA 22314

an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgement by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

Richard W. Wieking

CLERK

**MAR 22 2008**

DATE \_\_\_\_\_

  
(BY) DEPUTY CLERK **ANNA SPRINKLES**

AO 440 (Rev. 8/01) Summons in a Civil Action

<b>RETURN OF SERVICE</b>		
Service of the Summons and Complaint was made by me <sup>1</sup>		DATE
Name of SERVER		TITLE
<i>Check one box below to indicate appropriate method of service</i>		
<input type="checkbox"/>	Served Personally upon the Defendant. Place where served:	
<input type="checkbox"/>	Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left:	
<input type="checkbox"/>	Returned unexecuted:	
<input type="checkbox"/>	Other (specify):	
<b>STATEMENT OF SERVICE FEES</b>		
TRAVEL	SERVICES	TOTAL
<b>DECLARATION OF SERVER</b>		
<p style="text-align: center;">I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p>		
Executed on _____ <div style="text-align: center; margin-top: 5px;"><i>Date</i></div>	_____ <div style="text-align: center; margin-top: 5px;"><i>Signature of Server</i></div> _____ <div style="text-align: center; margin-top: 5px;"><i>Address of Server</i></div>	
(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure		

ORIGINAL  
FILED

MAR 22 2006

RICHARD W. WIEKING  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

Michael J. Miller, VA Bar No. 19171  
J. Christopher Ide, VA Bar No. 19307  
Mary F. Whitaker, VA Bar No. 27565  
MILLER AND ASSOCIATES  
105 North Alfred Street,  
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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
(SAN FRANCISCO DIVISION)

CRB

BEVERLY HASLAM, individually and  
on behalf of GLEN HASLAM, deceased,

Plaintiff,

v.

PFIZER INC., PHARMACIA  
CORPORATION, and G.D. SEARLE, LLC,

Defendants.

C 06

2145

Case No.

CIVIL COMPLAINT

JURY TRIAL DEMANDED

Beverly Haslam, as Personal Representative of the Estate of Glen Haslam,  
deceased, Plaintiff, through counsel and pursuant to applicable law and Utah's Wrongful Death  
Act, by and through her counsel, brings this action against Defendants PFIZER INC.,  
PHARMACIA CORPORATION, and G.D. SEARLE, LLC (hereafter collectively "Defendants")  
and alleges as follows:

1       **I. PARTIES**

2               1.       This is an action for damages arising from Defendants' design,  
3       manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe  
4       medication Valdecoxib, trade name BEXTRA® ("BEXTRA").

5               2.       Plaintiff and decedent were at all relevant times adult resident citizens of  
6       the State of Utah, and residents of Davis County. Plaintiff, Beverly Haslam, is the Personal  
7       Representative of the decedent's estate, is a resident of Utah, and is the proper party to bring this  
8       claim on behalf of the Estate and survivors of decedent. At the time of decedent's death,  
9       decedent left his surviving spouse: Beverly Haslam (Plaintiff).

10              3.       Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its  
11       principal place of business in New York, New York. In 2003, Pfizer acquired Pharmacia  
12       Corporation for nearly \$60 billion. At all relevant times Pfizer and/or its predecessors in interest  
13       were engaged in the business of designing, testing, manufacturing, packaging, marketing,  
14       distributing, promoting, and selling the drug Valdecoxib, under the trade name BEXTRA in  
15       California, Illinois, Utah, and nationwide.

16              4.       Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co.  
17       ("Searle") is a Delaware corporation with its principal place of business in Illinois. At all relevant  
18       times, Searle has been engaged in the business of marketing and selling BEXTRA nationwide and  
19       in California and Illinois. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all  
20       matters alleged within this Complaint.

21              5.       Defendant Pharmacia Corporation ("Pharmacia") is a Delaware  
22       corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia,  
23       and its predecessors in interest have been engaged in the business of designing, testing,  
24       manufacturing, packaging, marketing, distributing, promoting, and selling BEXTRA nationwide  
25       and in California and Illinois.

26       **II. JURISDICTION AND VENUE**

27              6.       This is an action for damages, which exceeds seventy-five thousand dollars  
28       (\$75,000.00).

1  
2 7. There is complete diversity of citizenship between the Plaintiff and  
3 Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A.  
4 § 1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and  
5 because there is complete diversity of citizenship between Plaintiff and Defendants.

6 8. Venue is proper in this United States Judicial District pursuant to  
7 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in  
8 the district, thereby receiving substantial financial benefit and profits the dangerous product in  
9 this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

10 9. At all relevant times herein, Defendants were in the business of designing,  
11 manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and  
12 selling their product, BEXTRA. Defendants at all times relevant hereto designed, developed,  
13 manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce  
14 (including California and Utah) the aforementioned prescription drug. Defendants do substantial  
15 business in the State of California and within this Federal Judicial District, advertise in this  
16 district, receive substantial compensation and profits from sales of BEXTRA in this District, and  
17 made material omissions and misrepresentations and breaches of warranties in this District so as  
18 to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged  
19 herein each defendant acted as the agent for each of the other defendants, or those defendant's  
20 predecessors in interest.

### 21 **III. INTERDISTRICT ASSIGNMENT**

22 10. Assignment to the San Francisco Division is proper as this action is related  
23 to *In Re: Bextra and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to  
24 the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6,  
25 2005.

### 26 **IV. FACTUAL BACKGROUND**

#### 27 **A. Facts Regarding Plaintiff**

28 11. Decedent was prescribed, and began taking, BEXTRA during 2003.



1  
2 12. As a direct and proximate result of using BEXTRA, Decedent suffered  
3 severe cardiovascular injuries. Specifically, on July 29, 2004, Decedent suffered an acute  
4 myocardial infarction ("heart attack"), which has caused his death.

5 13. Unaware of the risks presented by BEXTRA, or that BEXTRA was the  
6 cause of his injuries, Decedent continued to take BEXTRA until July 29, 2004.

7 14. Decedent and Decedent's healthcare providers were at the time of  
8 Decedent's heart attack and initial injury unaware—and could not have reasonably known or have  
9 learned through reasonable diligence—that such injury directly resulted from Defendants'  
10 negligent and otherwise culpable acts, omissions, and misrepresentations or from Decedent's  
11 ingestion of BEXTRA.

12 15. Decedent used BEXTRA in a proper and reasonably foreseeable manner  
13 and used it in a condition that was substantially the same as the condition in which it was  
14 manufactured and sold.

15 16. Decedent would not have used BEXTRA had Defendants properly  
16 disclosed the risks associated with the drug.

17 **B. Facts Regarding Bextra and Bextra's Market Launch**

18 17. Bextra is one of a class of pain medications called non-steroidal anti-  
19 inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade  
20 name Advil) are examples of well-known NSAIDs.

21 18. NSAIDs reduce pain by blocking the body's production of pain  
22 transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX  
23 enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and  
24 COX-2 enzymes.

25 19. In addition to decreasing inflammation, the prostaglandins that are  
26 supported by COX-1 enzymes are involved in the production of gastric mucus; this protects the  
27 stomach wall from the hydrochloric acid present in the stomach. It is generally accepted in the  
28 medical community that by blocking the COX-1 enzyme, the body's ability to protect gastric

1 tissue is hampered and as a result, can cause harmful gastrointestinal side effects, including  
2 stomach ulceration and bleeding.

3 20. Prostaglandin I2 is the predominant cyclooxygenase product in  
4 endothelium, inhibiting platelet aggregation (preventing clot formation), causing vasodilation,  
5 and preventing the proliferation of vascular smooth muscle. Whereas older NSAIDs inhibit  
6 Thromboxane A2 and Prostaglandin I2, the COX-2 inhibitors leave Thromboxane A2 unaffected.  
7 Thromboxane A2 is a potent platelet aggregator and vasoconstrictor, which is synthesized by  
8 platelets. Therefore, while the older NSAIDs suppress platelet aggregation and vasoconstriction,  
9 the COX-2 inhibitors support it.

10 21. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore  
11 pain by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected,  
12 traditional NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause  
13 blood clots, rather they actually reduce the risk of clots and help protect heart function.

14 22. Defendants and other pharmaceutical companies set out to remedy these  
15 ulcer and bleeding problems suffered by some NSAID users by developing "selective" inhibitors  
16 that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of  
17 gastric tissue while still reducing inflammation.

18 23. In making this decision, Defendants and their predecessors in interest either  
19 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2  
20 inhibition lowers prostacyclin levels and causes thromboxane A<sub>2</sub> to be uninhibited, causing blood  
21 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,  
22 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

23 24. Pfizer launched Celebrex, the first of the three major COX-2 inhibitor  
24 drugs, in early 1999 and initiated a massive marketing campaign to convince doctors and  
25 consumers of the superiority of their new "blockbuster" drug over less inexpensive NSAIDs. In  
26 May 1999, Merck & Co., Inc. ("Merck") launched Vioxx, its own selective COX-2 inhibitor.  
27  
28

1                   25. Seeking increased market share in this extremely lucrative market,  
2 Defendants, and their predecessors in interest, also sought approval of a "second generation"  
3 selective COX-2 inhibitor and filed for FDA approval of Bextra on January 16, 2001 for the  
4 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief  
5 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

6                   26. The FDA granted approval of the new drug on November 16, 2001, for two  
7 particular uses: (i) treatment of primary dysmenorrhea and (ii) relief for the signs and symptoms  
8 of osteoarthritis and rheumatoid arthritis.

9                   27. The FDA did not grant approval to market and promote Bextra for the  
10 management or prevention of acute pain.

11                   28. The FDA did not grant approval to promote Bextra as more effective than  
12 other NSAIDs in preventing clinically serious gastrointestinal events such as perforations, ulcers  
13 or gastric bleeding.

14                   29. Even without a label that allowed Defendants to legitimately claim superior  
15 safety, when Defendants, and their predecessors-in-interest, began marketing Bextra in early  
16 2002, Defendants and their representatives and agents misrepresented the safety profile of Bextra  
17 to consumers, including Plaintiff, the medical community, healthcare providers, and third party  
18 payers. Defendants proceeded to promote, market, sell, and distribute Bextra as a much safer and  
19 more effective pain reliever than other NSAIDs, such as aspirin, naproxen, and ibuprofen.

20                   **C. Facts Regarding Bextra's Safety and Defendants' Knowledge Thereof.**

21                   30. The potential for cardiovascular risk of selective COX-2 inhibitors was  
22 known to Defendants long before the FDA granted market approval in November 2, 2001. By  
23 1997, and prior to the submission of the New Drug Application (the "NDA") for Bextra,  
24 Defendants was aware that, by inhibiting COX-2, Bextra altered the homeostatic balance between  
25 prostacyclin synthesis and thromboxane and thereby, increased the prothrombotic effects of the  
26 drugs, causing blood clots to form in those who ingested it. *See Topol, E.J., et al., Risk of*  
27 *Cardiovascular Events Associated with Selective Cox-2 Inhibitors, JAMA, August 22, 2001 at*  
28

1 954. Although all COX-2 inhibitors have this mechanism of action, Bextra was the most  
2 selective COX-2 inhibitor proposed for approval. Accordingly, it had the greatest potential to  
3 cause adverse cardiovascular and cerebrovascular events.

4 31. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of  
5 Pennsylvania, reported in an editorial published in *The New England Journal of Medicine* on  
6 October 21, 2004, that it was known as early as 1999 that selective COX-2 inhibitors, such as  
7 Bextra, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet  
8 aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

9 32. Nevertheless, on January 16, 2001, Defendants submitted an NDA to the  
10 FDA for Bextra, omitting information about the extent of the risks associated with Bextra.  
11 Without a complete picture of the potential hazards associated with the drug, the FDA approved  
12 Bextra on or about November 16, 2001.

13 33. Based on the studies performed on Celebrex, Vioxx, Bextra, and other  
14 COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely  
15 conducted, Defendants knew when Bextra was being developed and tested that selective COX-2  
16 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific  
17 additional threat to anyone with existing heart disease or cardiovascular risk factors. Studies  
18 show that selective COX-2 inhibitors, including Bextra, decrease blood levels of a prostacyclin.  
19 When those levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart  
20 attack, and stroke.

21 34. On December 9, 2004, the FDA issued new information on side effects  
22 associated with the use of Bextra and required the addition of certain warnings to, and the  
23 strengthening of other warnings on, the Bextra label. The enhanced warnings followed in the  
24 wake of the results of additional cardiovascular studies performed by Defendants, as well as  
25 numerous complaints to the FDA regarding severe skin reactions.

26 35. Yet well prior to this warning, Defendants had knowledge of the coronary  
27 and cardiovascular safety risks of Bextra from several studies. *See e.g., Otto, E.O., Efficacy and*  
28

1 *Safety of the Cyclooxygenase 2 Inhibitors Parecoxib and Valdecoxib in Patients Undergoing*  
2 *Coronary Artery Bypass Surgery, The Journal of Thoracic and Cardiovascular Surgery*, June  
3 2003 at 1481.

4 36. Even Defendants' own (and Pfizer funded) post- drug approval meta-  
5 analysis study (first presented on March 31, 2003 and again on May 15, 2003) included this data  
6 showing an increased cardiovascular risk in patients treated with Bextra after undergoing  
7 coronary artery bypass graft surgery. Observed events included heart attack, stroke, and blood  
8 clots in the legs and lungs. The results were particularly relevant and striking as each of the study  
9 participants who were a post-bypass surgery patient was taking anti-clotting agents at the time  
10 their exposure to Bextra was being tracked.

11 37. In mid-January 2005, a peer-reviewed paper from the University of  
12 Pennsylvania found that in patients having heart bypass surgery, those who took Bextra in the  
13 intravenous form, parecoxib, as opposed to a placebo, were three times more likely to have a  
14 heart attack or stroke.

15 38. From February 16-18, 2005, the FDA's Drug Safety and Risk Management  
16 Advisory Committee and the Arthritis Drug Advisory Committee met jointly to further examine  
17 the safety of COX-2 inhibitors. There, FDA Office of Drug Safety Officer David Graham  
18 testified that selective COX-2 inhibitors increase the risk for adverse cardiovascular events at  
19 about the same rate as cigarette smoking, hypertension, and diabetes.

20 39. Despite years of studies on selective COX-2 inhibitors, as well as the  
21 disturbing new studies specifically analyzing the risks of Bextra, Defendants failed to take any  
22 action to protect the health and welfare of patients, but instead, continued to promote the drug for  
23 sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis  
24 Drug Advisory Committee meetings.

25 40. On April 7, 2005, the FDA finally insisted that Defendants "voluntarily  
26 withdraw" Bextra from the U.S. market, stating:

27 "... the Agency has concluded that the overall risk versus benefit  
28 profile of Bextra is unfavorable. This conclusion is based on the

1 potential increased risk for serious cardiovascular (CV) adverse  
2 events, which appears to be a class effect of non-steroidal anti-  
3 inflammatory drugs (NSAIDs) (excluding aspirin), an increased  
4 risk of serious skin reactions (e.g. toxic epidermal necrolysis,  
Stevens-Johnson syndrome, erythema multiforme) compared to  
other NSAIDs, and the fact that Bextra has not been shown to offer  
any unique advantage over the other available NSAIDs."

5 41. FDA Alert for Healthcare Professionals, April 7, 2005.

6 Continuing, the FDA noted:

7 "Bextra has been demonstrated to be associated with an  
8 increased risk of serious adverse CV events in two short-term trials  
9 in patients immediately post-operative from coronary artery bypass  
10 graft (CABG) surgery . . . . FDA has concluded that it is reasonable  
11 to extrapolate the adverse CV risk information for Bextra from the  
12 short-term CABG trials to chronic use given the fact that other  
13 COX-2 selective NSAIDs have been shown in long-term controlled  
14 clinical trials to be associated with an increased risk of serious  
15 adverse CV events (e.g., death, MI, stroke), and the well described  
16 risk of serious, and often life-threatening gastrointestinal  
17 bleeding . . . . To date, there have been no studies that demonstrate  
18 an advantage of Bextra over other NSAIDs that might offset the  
19 concern about the[] serous skin risks, such as studies that show a GI  
20 safety benefit, better efficacy compared to other products, or  
21 efficacy in a setting of patients who are refractory to treatment with  
22 other products."

23 42. The scientific data available during and after Bextra's approval process  
24 made clear to Defendants that their formulation of Bextra would cause a higher risk of blood  
25 clots, stroke and/or myocardial infarctions among Bextra consumers, alerting them to the need to  
26 do additional and adequate safety studies.

27 43. As stated by Dr. Topol on October 21, 2004, in *The New England Journal*  
28 *of Medicine*, outlining Defendants' failure to have conducted the necessary trials before  
marketing to humans " . . . it is mandatory to conduct a trial specifically assessing cardiovascular  
risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with  
established coronary artery disease, who frequently have coexisting osteoarthritis requiring  
medication and have the highest risk of further cardiovascular events."

44. Dr. Topol was also the author on the study published in August 2001 in  
JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in  
persons who used COX-2 inhibitors.



1                   45. Based upon readily available scientific data, Defendants knew, or should  
2 have known, that their pre-approval testing of Bextra did not adequately represent the cross-  
3 section of individuals who were intended consumers and therefore, likely to take Bextra.  
4 Therefore, Defendants' testing and studies were grossly inadequate. *See, e.g.*, PDR entry for  
5 Bextra (noting that: "**Platelets:** In four clinical studies with young and elderly ( $\geq 65$  years)  
6 subjects, single and multiple doses up to 7 day mg BID had no effect on platelet aggregation").

7                   46. Had Defendants done adequate testing prior to approval and "market  
8 launch," rather than the extremely short duration studies done on the small size patient base that  
9 was actually done) Pharmacia and Searle's scientific data would have revealed significant  
10 increases in incidence of strokes and myocardial infarctions among the intended and targeted  
11 population of Bextra consumers. Adequate testing would have shown that Bextra possessed  
12 serious side effects for individuals such as Plaintiff. Defendants should have taken appropriate  
13 measures to ensure that their defectively designed product would not be placed in the stream of  
14 commerce and/or should have provided full and proper warnings accurately and fully reflecting  
15 the scope and severity of symptoms of those side effects should have been made.

16                   47. In fact, post-market approval data did reveal increased risks of clotting,  
17 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants  
18 in order for them to gain significant profits from continued Bextra sales.

19                   48. Defendants' failure to conduct adequate testing and/or additional testing  
20 prior to "market launch" was based upon their desire to generate maximum financial gains for  
21 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2  
22 inhibitor market.

23                   49. At the time Defendants manufactured, advertised, and distributed Bextra to  
24 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding  
25 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants  
26 knew that if such increased risks were disclosed, consumers such as Plaintiff would not purchase  
27 Bextra, but instead would purchase other cheaper and safer NSAIDs.  
28

1           **D.     Facts Regarding Defendants' Marketing and Sale of Bextra**

2           50.     Plaintiff and at all times relevant herein, Defendants engaged in a  
3     marketing campaign with the intent that consumers would perceive Bextra as a safer and better  
4     drug than its other NSAIDs and, therefore, purchase Bextra.

5           51.     Defendants widely and successfully marketed Bextra throughout the  
6     United States by, among other things, conducting promotional campaigns that misrepresented the  
7     efficacy of Bextra in order to induce a widespread use and consumption. Bextra was represented  
8     to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made  
9     misrepresentations by means of media advertisements, and statements contained in sales literature  
10    provided to Plaintiff's prescribing physicians.

11          52.     Despite knowledge of the dangers presented by Bextra, Defendants and  
12    Defendants' predecessors in interest, through their officers, directors and managing agents for the  
13    purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy  
14    the known defects of Defendants' product, Bextra, and failed to warn the public, including  
15    Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,  
16    Bextra. Defendants and their officers, agents and managers intentionally proceeded with the  
17    inadequate safety testing, and then the manufacturing, sale and marketing of Defendants' product,  
18    Bextra, knowing that persons would be exposed to serious potential danger, in order to advance  
19    their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a  
20    conscious disregard for the safety of the public and particularly of Plaintiff.

21          53.     In an elaborate and sophisticated manner, Defendants aggressively  
22    marketed Bextra directly to consumers and medical professionals (including physicians and  
23    leading medical scholars) in order to leverage pressure on third party payers, medical care  
24    organizations, and large institutional buyers (e.g., hospitals) to include Bextra on their  
25    formularies. Faced with the increased demand for the drug by consumers and health care  
26    professionals that resulted from Defendants' successful advertising and marketing blitz, third  
27    party payers were compelled to add Bextra to their formularies. Defendants' marketing campaign  
28



1 specifically targeted third party payers, physicians, and consumers, and was designed to convince  
2 them of both the therapeutic and economic value of Bextra.

3 54. Defendants represented that Bextra was similar to ibuprofen and naproxen  
4 but was superior because it lacked any of the common gastrointestinal adverse side effects  
5 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,  
6 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with  
7 long-term use. Defendants promoted Bextra as a safe and effective alternative that would not  
8 have the same deleterious and painful impact on the gut, but that would be just as effective, if not  
9 more so, for pain relief.

10 55. Bextra possessed dangerous and concealed or undisclosed side effects,  
11 including the increased risk of serious cardiovascular events, such as heart attacks, unstable  
12 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as  
13 strokes. In addition, Bextra was no more effective than traditional and less expensive NSAIDs  
14 and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal  
15 bleeding. Defendants chose not to warn about these risks and dangers.

16 56. Defendants knew of these risks before the U.S. Food and Drug  
17 Administration (the "FDA") approved Bextra for sale on November 16, 2001, but Defendants  
18 ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied  
19 inefficacy in its promotion, advertising, marketing, and sale of Bextra. Defendants' omission,  
20 suppression, and concealment of this important information enabled Bextra to be sold to, and  
21 purchased, or paid for by, the Consumers at a grossly inflated price.

22 57. Consequently, Bextra captured a large market share of anti-inflammatory  
23 drugs prescribed for and used by patients. In 2002 alone (after a drug launch in March of 2002),  
24 sales of Bextra exceeded \$1.5 billion, despite the significantly higher cost of Bextra as compared  
25 to other pain relievers in the same family of drugs.

26 58. It was not until April 7, 2005, that Defendants finally acknowledged  
27 Bextra's deleterious side effects and announced that they were withdrawing the drug from the  
28

1 worldwide market based on what it misleadingly termed "new" and "unexpected" evidence  
2 linking Bextra to an increased risk of heart attacks and strokes.

3 59. Had Defendants done adequate testing prior to approval and "market  
4 launch," Pharmacia's scientific data would have revealed significant increases in stroke and  
5 myocardial infarction amongst the intended population of BEXTRA consumers. Adequate  
6 testing would have shown that BEXTRA possessed serious side effects. Defendants should have  
7 taken appropriate measures to ensure that their defectively designed product would not be placed  
8 in the stream of commerce and/or should have provided full and proper warnings accurately and  
9 fully reflecting the scope and severity of symptoms of those side effects should have been made.

10 60. In fact, post-market approval data did reveal increased risks of clotting,  
11 stroke and myocardial infarction, but this information was intentionally suppressed by Defendants  
12 in order for them to gain significant profits from continued BEXTRA sales.

13 61. Defendants' failure to conduct adequate testing and/or additional testing  
14 prior to "market launch" was based upon their desire to generate maximum financial gains for  
15 themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2  
16 inhibitor market.

17 62. At the time Defendants manufactured, advertising, and distributed  
18 BEXTRA to consumers, Defendants intentionally or recklessly ignored and/or withheld  
19 information regarding the increased risks of hypertension, stroke and/or myocardial infarctions  
20 because Defendants knew that if such increased risks were disclosed, consumers such as plaintiff  
21 would not purchase BEXTRA, but instead would purchase other cheaper and safer NSAID drugs.

22 63. At all times relevant herein, Defendants engaged in a marketing campaign  
23 with the intent that consumers, including plaintiff, and their doctors would perceive BEXTRA as  
24 a better drug than its competitors and, therefore, purchase BEXTRA.

25 64. Defendants widely and successfully marketed BEXTRA throughout the  
26 United States by, among other things, conducting promotional campaigns that misrepresented the  
27 efficacy of BEXTRA in order to induce a widespread use and consumption. BEXTRA was  
28

1 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.  
 2 Defendants made misrepresentations by means of media advertisements, and statements  
 3 contained in sales literature provided to Plaintiff's prescribing physicians.

4 65. Prior to manufacturing, sale and distribution of BEXTRA, Defendants,  
 5 through their officers, director and managing agents, had notice and knowledge from several  
 6 sources, that BEXTRA presented substantial and unreasonable risks of harm to the consumer. As  
 7 such, BEXTRA consumers, including Plaintiff, were unreasonably subject to risk of injury or  
 8 death from the consumption of Defendants' product, BEXTRA.

9 Despite such knowledge, Defendants and Defendants' predecessors in interest, through their  
 10 officers, directors and managing agents for the purpose of increasing sales and enhancing its  
 11 profits, knowingly and deliberately failed to remedy the known defects of Defendants' product,  
 12 BEXTRA, and failed to warn the public, including Plaintiff, of the serious risk of injury  
 13 occasioned by the defects inherent in Defendants' product, BEXTRA. Defendants and their  
 14 officers, agents and managers intentionally proceeded with the inadequate testing, and then the  
 15 manufacturing, sale and marketing of Defendants' product, BEXTRA, knowing that persons  
 16 would be exposed to serious potential danger, in order to advance their own pecuniary interests.  
 17 Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety  
 18 of the public and particularly of Plaintiff.

## 19 CLAIMS FOR RELIEF

### 20 FIRST CLAIM FOR RELIEF:

#### 21 Negligence

22 66. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
 23 as if fully set forth herein.

24 67. Defendants owed Decedent a duty to exercise reasonable care when  
 25 designing, manufacturing, marketing, advertising, distributing, and selling BEXTRA. This duty  
 26 included the duty not to introduce a pharmaceutical drug, such as BEXTRA, into the stream of  
 27  
 28

1 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side  
2 effects.

3  
4 68. At all relevant times to this action, Defendants owed a duty to properly  
5 warn Decedent and the Public of the risks, dangers and adverse side effects of their  
6 pharmaceutical drug BEXTRA.

7 69. Defendants breached their duties by failing to exercise ordinary care in the  
8 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
9 marketing, promotion, advertising and selling of BEXTRA, including:

10 a. failing to use due care in the preparation and development of  
11 BEXTRA to prevent the aforementioned risk of injuries to individuals when the drugs were  
12 ingested;

13 b. failing to use due care in the design of BEXTRA to prevent the  
14 aforementioned risk of injuries to individuals when the drugs were ingested;

15 c. failing to conduct adequate pre-clinical testing and research to  
16 determine the safety of BEXTRA;

17 d. failing to conduct adequate post-marketing surveillance and  
18 exposure studies to determine the safety of BEXTRA;

19 e. failing to completely, accurately and in a timely fashion, disclose  
20 the results of the pre-marketing testing and post-marketing surveillance and testing to Decedent,  
21 consumers, the medical community, and the FDA;

22 f. failing to accompany BEXTRA with proper warnings regarding all  
23 possible adverse side effects associated with the use of BEXTRA;

24 g. failing to use due care in the manufacture, inspection, and labeling  
25 of BEXTRA to prevent the aforementioned risk of injuries to individuals who used BEXTRA;

26 h. failing to use due care in the promotion of BEXTRA to prevent the  
27 aforementioned risk of injuries to individuals when the drugs were ingested;

1 i. failing to use due care in the sale and marketing of BEXTRA to  
2 prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

3 j. failing to use due care in the selling of BEXTRA to prevent the  
4 aforementioned risk of injuries to individuals when the drugs were ingested;

5 k. failing to provide adequate and accurate training and information to  
6 the sales representatives who sold BEXTRA;

7 l. failing to provide adequate and accurate training and information to  
8 healthcare providers for the appropriate use of BEXTRA; and

9 m. being otherwise reckless, careless and/or negligent.

10 70. Despite the fact that Defendants knew or should have known that  
11 BEXTRA caused unreasonable and dangerous side effects which many users would be unable to  
12 remedy by any means, Defendants continued to promote and market BEXTRA to consumers,  
13 including Decedent, when safer and more effective methods of pain relief were available.

14 71. Defendants were, or should have been, had they exercised reasonable care,  
15 in possession of evidence demonstrating that BEXTRA caused serious side effects. Nevertheless,  
16 they continued to market their products by providing false and misleading information with  
17 regard to the safety and efficacy of BEXTRA.

18 72. Defendants knew or should have known that consumers such as Decedent  
19 would foreseeably suffer injury as a result of their failure to exercise ordinary care as described  
20 above.

21 73. As a direct and proximate consequence of Defendants' acts, omissions, and  
22 misrepresentations described herein, the Plaintiff and her children suffered loss of support and  
23 services and endured mental pain and suffering and loss of consortium of her husband and their  
24 father. The losses are permanent and continuing in nature. In addition, the estate suffered a loss  
25 of net accumulations due to the premature death of Decedent, and the personal representative  
26 incurred medical and funeral expenses for the burial and funeral services of the decedent.  
27 Decedent sustained serious cardiovascular injuries and death. Decedent required healthcare and  
28

1 services incurring direct medical losses and costs including care for hospitalization, physician  
2 care, monitoring, treatment, medications, and supplies.

3 74. Defendants' conduct was committed with knowing, conscious, wanton,  
4 willful, and deliberate disregard for the value of human life and the rights and safety of  
5 consumers, including Decedent, thereby entitling Plaintiff to punitive and exemplary damages so  
6 as to punish Defendants and deter them from similar conduct in the future.

7 75. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
8 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
9 suit and attorneys' fees and such other and further relief as this Court deems just and proper.  
10

11 **SECOND CLAIM FOR RELIEF:**  
12 **Strict Liability**

13 76. Plaintiff incorporates by reference all previous paragraphs of this  
14 Complaint as if fully set forth herein and further alleged as follows:

15 77. At all times relevant to this action, Defendants were suppliers of BEXTRA,  
16 placing the drug into the stream of commerce. BEXTRA was expected to and did reach Decedent  
17 without substantial change in the condition in which it was manufactured and sold.

18 78. BEXTRA was unsafe for normal or reasonably anticipated use.

19 79. BEXTRA was defective in design or formulation because when it left the  
20 hands of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous  
21 than an ordinary consumer would expect. BEXTRA was also defective and unreasonably  
22 dangerous in that the foreseeable risk of injuries from BEXTRA exceeded the benefits associated  
23 with the design and/or formulation of the product.

24 80. Bextra is unreasonably dangerous: a) in construction or composition; b) in  
25 design; c) because an adequate warning about the product was not provided; and d) because it  
26 does not conform to an express warranty of the manufacturer about the product.  
27  
28



1                   81. The characteristics of Bextra that render it unreasonably dangerous existed  
2 at the time the product left the control of the manufacturer or resulted from a reasonably  
3 anticipated alteration or modification of the product.

4                   82. The BEXTRA manufactured and supplied by Defendants was also  
5 defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and  
6 inadequate reporting regarding the results of the clinical trials, testing and study. Defendants  
7 failed to perform adequate testing before exposing Decedent to the medication, testing which  
8 would have shown that BEXTRA had the potential to cause serious side effects including strokes  
9 like that which affected Decedent.

10                  83. The BEXTRA manufactured and supplied by Defendants was defective  
11 due to inadequate post-marketing warnings or instructions because, after Defendants knew or  
12 should have known of the risk of injuries from BEXTRA, they failed to provide adequate  
13 warnings to the medical community and the consumers, to whom they were directly marketing  
14 and advertising BEXTRA; and, further, it continued to affirmatively promote BEXTRA as safe  
15 and effective.

16                  84. BEXTRA was manufactured, distributed, tested, sold, marketed, advertised  
17 and promoted defectively by Defendants, and as a direct and proximate cause of Defendants'  
18 defective design of BEXTRA, Decedent used BEXTRA rather than other safer and cheaper  
19 NSAIDs. As a result, Decedent suffered the personal injuries described above.

20                  85. Information given by Defendants to the medical community and to the  
21 consumers concerning the safety and efficacy of BEXTRA, especially the information contained  
22 in the advertising and promotional materials, did not accurately reflect the potential side effects of  
23 BEXTRA.

24                  86. Had adequate warnings and instructions been provided, Decedent would  
25 not have taken BEXTRA as he did, and would not have been at risk of the harmful side effects  
26 described herein.

1                   87. Defendants acted with conscious and deliberate disregard of the  
2 foreseeable harm caused by BEXTRA.

3                   88. Decedent could not, through the exercise of reasonable care, have  
4 discovered BEXTRA's defects or perceived the dangers posed by the drug.

5                   89. As a direct and proximate consequence of Defendants' acts, omissions, and  
6 misrepresentations described herein, the Plaintiff and her children suffered loss of support and  
7 services and endured mental pain and suffering and loss of consortium of her husband and their  
8 father. The losses are permanent and continuing in nature. In addition, the estate suffered a loss  
9 of net accumulations due to the premature death of Decedent, and the personal representative  
10 incurred medical and funeral expenses for the burial and funeral services of the decedent.  
11 Decedent sustained serious cardiovascular injuries and death. Decedent required healthcare and  
12 services incurring direct medical losses and costs including care for hospitalization, physician  
13 care, monitoring, treatment, medications, and supplies.

14                   90. Defendants' conduct was committed with knowing, conscious, wanton,  
15 willful, and deliberate disregard for the value of human life and the rights and safety of  
16 consumers, including Decedent, thereby entitling Plaintiff to punitive and exemplary damages so  
17 as to punish Defendants and deter them from similar conduct in the future.

18                   91. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
19 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
20 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

21  
22                   **THIRD CLAIM FOR RELIEF:**  
23                   **Breach of Express Warranty**

24                   92. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
25 as if fully set forth herein.

26                   93. Defendants expressly represented to Decedent and other consumers and the  
27 medical community that BEXTRA was safe and fit for its intended purposes, that it was of  
28



1 merchantable quality, that it did not produce any dangerous side effects, particularly any  
2 unwarmed-of side effects, and that it was adequately tested.

3 94. These warranties came in the form of:

4 a. Defendants' public written and verbal assurances of the safety and  
5 efficacy of BEXTRA;

6 b. Press releases, interviews and dissemination via the media of  
7 promotional information, the sole purpose of which was to create an increased demand for  
8 BEXTRA, which failed to warn of the risk of injuries inherent to the ingestion of BEXTRA,  
9 especially to the long-term ingestion of BEXTRA;

10 c. Verbal and written assurances made by Defendants regarding  
11 BEXTRA and downplaying the risk of injuries associated with the drug;

12 d. False and misleading written information, supplied by Defendants,  
13 and published in the Physician's Desk Reference on an annual basis, upon which physicians  
14 relied in prescribing BEXTRA during the period of Decedent's ingestion of BEXTRA, and;

15 e. advertisements.

16 95. The documents referred to above were created by and at the direction of  
17 Defendants.

18 96. Defendants knew or had reason to know that BEXTRA did not conform to  
19 these express representations in that BEXTRA is neither as safe nor as effective as represented,  
20 and that BEXTRA produces serious adverse side effects.

21 97. BEXTRA did not and does not conform to Defendants' express  
22 representations because it is not safe, has numerous and serious side effects, including unwarmed-  
23 of side effects, and causes severe and permanent injuries.

24 98. Decedent, other consumers, and the medical community relied upon  
25 Defendants' express warranties.

26 99. As a direct and proximate consequence of Defendants' acts, omissions, and  
27 misrepresentations described herein, the Plaintiff and her children suffered loss of support and  
28

1 services and endured mental pain and suffering and loss of consortium of her husband and their  
 2 father. The losses are permanent and continuing in nature. In addition, the estate suffered a loss  
 3 of net accumulations due to the premature death of Decedent, and the personal representative  
 4 incurred medical and funeral expenses for the burial and funeral services of the decedent.

5 Decedent sustained serious cardiovascular injuries and death. Decedent required healthcare and  
 6 services incurring direct medical losses and costs including care for hospitalization, physician  
 7 care, monitoring, treatment, medications, and supplies.

8 100. Defendants' conduct was committed with knowing, conscious, wanton,  
 9 willful, and deliberate disregard for the value of human life and the rights and safety of  
 10 consumers, including Decedent, thereby entitling Plaintiff to punitive and exemplary damages so  
 11 as to punish Defendants and deter them from similar conduct in the future.

12 101. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
 13 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
 14 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

15  
 16 **FOURTH CLAIM FOR RELIEF:**  
**Breach of Implied Warranty**

17 102. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
 18 as if fully set forth herein.

19 103. Defendants manufactured, distributed, advertised, promoted, and sold  
 20 BEXTRA.

21 104. At all relevant times, Defendants knew of the use for which BEXTRA was  
 22 intended and impliedly warranted the product to be of merchantable quality and safe and fit for  
 23 such use.

24 105. Defendants were aware that consumers, including Decedent, would use  
 25 BEXTRA for treatment of pain and inflammation and for other purposes.

26 106. Decedent and the medical community reasonably relied upon Defendants'  
 27 judgment and expertise to only sell them or allow them to prescribe BEXTRA only if it was  
 28

1 indeed of merchantable quality and safe and fit for its intended use. Consumers, including  
2 Decedent, and the medical community, reasonably relied upon Defendants' implied warranty for  
3 BEXTRA.

4 107. BEXTRA reached consumers, including Decedent, without substantial  
5 change in the condition in which it was manufactured and sold by Defendants.

6 108. Defendants breached their implied warranty to consumers, including  
7 Decedent; BEXTRA was not of merchantable quality or safe and fit for its intended use.

8 109. As a direct and proximate consequence of Defendants' acts, omissions, and  
9 misrepresentations described herein, the Plaintiff and her children suffered loss of support and  
10 services and endured mental pain and suffering and loss of consortium of her husband and their  
11 father. The losses are permanent and continuing in nature. In addition, the estate suffered a loss  
12 of net accumulations due to the premature death of Decedent, and the personal representative  
13 incurred medical and funeral expenses for the burial and funeral services of the decedent.  
14 Decedent sustained serious cardiovascular injuries and death. Decedent required healthcare and  
15 services incurring direct medical losses and costs including care for hospitalization, physician  
16 care, monitoring, treatment, medications, and supplies.

17 110. Defendants' conduct was committed with knowing, conscious, wanton,  
18 willful, and deliberate disregard for the value of human life and the rights and safety of  
19 consumers, including Decedent, thereby entitling Plaintiff to punitive and exemplary damages so  
20 as to punish Defendants and deter them from similar conduct in the future.

21 111. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
22 compensatory damages and punitive and exemplary damages together with interest, the costs of  
23 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

24  
25 **FIFTH CLAIM FOR RELIEF:**  
26 **Fraudulent Misrepresentation & Concealment**

27 112. Plaintiff incorporates by reference all of the paragraphs of this Complaint  
28 as if fully set forth herein.

1  
2 113. Defendants' superior knowledge and expertise, their relationship of trust  
3 and confidence with doctors and the public, their specific knowledge regarding the risks and  
4 dangers of BEXTRA, and their intentional dissemination of promotional and marketing  
5 information about BEXTRA for the purpose of maximizing its sales, each gave rise to the  
6 affirmative duty to meaningfully disclose and provide all material information about BEXTRA's  
7 risks and harms to doctors and consumers.

8 114. Defendants made fraudulent affirmative misrepresentations with respect to  
9 BEXTRA in the following particulars:

10 f. Defendants represented through their labeling, advertising,  
11 marketing materials, detail persons, seminar presentations, publications, notice letters, and  
12 regulatory submissions that BEXTRA had been tested and found to be safe and effective for the  
13 treatment of pain and inflammation; and

14 g. Defendants represented that BEXTRA was safer than other  
15 alternative medications.

16 115. Defendants made affirmative misrepresentations; and fraudulently,  
17 intentionally and/or recklessly concealed material adverse information regarding the safety and  
18 effectiveness of BEXTRA.

19 116. Defendants made these misrepresentations and actively concealed adverse  
20 information at a time when Defendants knew or had reason to know that BEXTRA had defects  
21 and was unreasonably dangerous and was not what Defendants had represented to the medical  
22 community, the FDA and the consuming public, including Decedent.

23 117. Defendants omitted, suppressed and/or concealed material facts concerning  
24 the dangers and risk of injuries associated with the use of BEXTRA including, but not limited to,  
25 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'  
26 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the  
27 serious nature of the risks associated with the use of BEXTRA in order to increase its sales.  
28

1           118. The representations and concealment were undertaken by Defendants with  
2 an intent that doctors and patients, including Decedent, rely upon them.

3           119. Defendants' representations and concealments were undertaken with the  
4 intent of defrauding and deceiving Decedent, other consumers, and the medical community to  
5 induce and encourage the sale of BEXTRA.

6           120. Defendants' fraudulent representations evinced their callous, reckless,  
7 willful, and depraved indifference to the health, safety, and welfare of consumers, including  
8 Decedent.

9           121. Decedent's physician and Decedent relied on and were induced by  
10 Defendants' misrepresentations, omissions, and/or active concealment of the dangers of  
11 BEXTRA in selecting BEXTRA treatment.

12           122. Decedent and the treating medical community did not know that the  
13 representations were false and were justified in relying upon Defendants' representations.

14           123. Had Decedent been aware of the increased risk of side effects associated  
15 with BEXTRA and the relative efficacy of BEXTRA compared with other readily available  
16 medications, Decedent would not have taken BEXTRA as he did.

17           124. As a direct and proximate consequence of Defendants' acts, omissions, and  
18 misrepresentations described herein, the Plaintiff and her children suffered loss of support and  
19 services and endured mental pain and suffering and loss of consortium of her husband and their  
20 father. The losses are permanent and continuing in nature. In addition, the estate suffered a loss  
21 of net accumulations due to the premature death of Decedent, and the personal representative  
22 incurred medical and funeral expenses for the burial and funeral services of the decedent.  
23 Decedent sustained serious cardiovascular injuries and death. Decedent required healthcare and  
24 services incurring direct medical losses and costs including care for hospitalization, physician  
25 care, monitoring, treatment, medications, and supplies.

26           125. Defendants' conduct was committed with knowing, conscious, wanton,  
27 willful, and deliberate disregard for the value of human life and the rights and safety of  
28

1 consumers, including Decedent, thereby entitling Plaintiff to punitive and exemplary damages so  
2 as to punish Defendants and deter them from similar conduct in the future.

3 126. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
4 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
5 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.  
6

7 **SIXTH CLAIM FOR RELIEF**  
8 **(Unjust Enrichment)**

9 127. Plaintiff incorporates by reference all previous paragraphs of this  
10 Complaint as if fully set forth herein.

11 128. At all times relevant to this action, Defendants were the manufacturers,  
12 sellers, and/or suppliers of BEXTRA.

13 129. Decedent paid for BEXTRA for the purpose of managing his pain safely  
14 and effectively.

15 130. Defendants have accepted payment from Decedent for the purchase of  
16 BEXTRA.

17 131. Decedent did not received the safe and effective pharmaceutical product  
18 for which she paid.

19 132. It is inequitable and unjust for Defendants to retain this money because the  
20 Decedent did not in fact receive the product Defendant represented BEXTRA to be.

21 133. WHEREFORE, Plaintiff demands judgment against Defendants and seeks  
22 equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court  
23 deems just and proper.

24  
25 **PRAYER FOR RELIEF**

26 WHEREFORE, Plaintiff requests the following relief:

27 134. General damages in excess of the jurisdictional amount of this Court;  
28

- 1 135. Consequential damages;  
2 136. Disgorgement of profits;  
3 137. Restitution;  
4 138. Punitive and exemplary damages;  
5 139. Pre-judgment and post-judgment interest as provided by law;  
6 140. Recovery of Decedent's costs including, but not limited to, discretionary  
7 Court costs of these causes, and those costs available under the law, as well as expert fees and  
8 attorneys' fees and expenses, and costs of this action; and  
9 141. Such other and further relief as the Court deems just and proper.  
10

11 Dated: March 21, 2006

Respectfully submitted,

12 MILLER & ASSOCIATES  
13

14 By:   
15 J. CHRISTOPHER IDE

16 Michael J. Miller, VA Bar No. 19171  
17 J. Christopher Ide, VA Bar No. 19307  
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24

25 Attorneys for Plaintiff  
26  
27  
28

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: March 21, 2006

Respectfully submitted,

MILLER & ASSOCIATES

By:   
J. CHRISTOPHER IDE

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